REMARKS

In the Office Action, claims 1-43 are rejected under 35 U.S.C. § 112, first paragraph; claims 1-4 are rejected under 35 U.S.C. § 102; claims 41 and 42 are rejected under 35 U.S.C. § 103; and claims 29-36 and 41-42 are provisionally rejected under 35 U.S.C. § 101. Claims 1, 10, 23, 34, 37, 41 and 43 have been amended. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made**." Applicant respectfully submits that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, claims 1-43 are rejected under 35 U.S.C. § 112, first paragraph. The Patent Office essentially asserts that the claims are not enabling with respect to the use of the claim terms "a compound characterized by its ability to disrupt endogenous compounds which stimulate dilator muscle of the eye" and "a first active compound characterized by its ability to reduce dilation of human eye."

In the spirit of cooperation and to expedite prosecution thereof, claims 1, 10, 23, 34, 37, 41 and 43 have been amended as previously discussed. As amended, each of these independent claims includes an alpha 1 antagonist compound. Thus, each of the dependent claims that depend therefrom includes this features as well. Therefore, Applicant believes that the claimed invention as amended and discussed above fully complies with 35 U.S.C. § 112, first paragraph.

With respect to the rejection of claims 18 and 29 under § 112, first paragraph, Applicant believes that these claims are enabling as presently pending. Independent claim 18 recites a method for optimizing pupil diameter in dim light by minimizing its dilation in response to less light wherein the method includes administering a therapeutically effective amount of an imidazoline to an eye of a person in need thereof. Independent claim 29 recites a method for optimizing pupil diameter in dim light by minimizing its dilation in response to less light wherein the method includes the steps of administering to an unmedicated human eye a therapeutically effective amount of an alpha 1 antagonist to an eye of a person in need thereof. Support for these claims and the amended claims as discussed above is provided, for example, in the specification on page 3, at lines 23-26. Therefore, Applicant believes that the requirements of § 112, first paragraph, have been satisfied.

Accordingly, Applicant respectfully requests that the rejection of claims 1-43 under 35 U.S.C. § 112, first paragraph, be withdrawn.

In the Office Action, claims 1-4 are rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 4,443,441 ("*Galin*"). The Patent Office essentially asserts that the *Galin* reference discloses each and every features of the claimed invention.

Applicant believes that this rejection is improper. Of the pending claims at issue, claim 1 is the sole independent claim. Independent claim 1 relates to an ophthalmic formulation. The formulation includes a first active compound that includes an alpha 1 antagonist capable of reducing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent a compound and generating a redness response of about +1 or less on a scale of 0 to +4.

The formulations of the claimed invention can be used to optimize pupil size to obtain enhanced vision acuity in dim light by reducing the pupil diameter in dim light without causing a clinically significant reduction in pupil size in bright light, particularly when the pupil size does not need to be reduced to some extent as required under dim light. Thus, the formulations of the claimed invention can act to decrease the difference between the diameter of pupil dilation in dim light and the diameter of pupil dilation in bright light. This can be done by decreasing the amount of dilation the human eye will undergo when exposed to dim light. See, Specification, for example, page 14.

In contrast, Applicant believes that *Galin* fails to disclose or arguably suggest at least a number of features of the claimed invention. Of course, the Court of Appeals for the Federal Circuit has held that "invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference . . . there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic and Research Foundation v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

For example, *Galin* merely relates to the use of alpha adrenergic blocking agents to aid in the fixation of interocular lenses. Indeed, *Galin* further discloses that this type of pupillary activity can reduce eccentric synechia formation and lens dislocation. See, *Galin*, column 1, line 61-67.

In contrast, the formulations of the claimed invention contain a first active compound that includes an alpha 1 antagonist. This allows the formulations of the claimed invention to decrease the difference between the diameter of pupil dilation in dim light and the diameter of pupil dilation in bright light. This can be done by decreasing the amount of dilation the human eye will undergo when exposed to dim light as previously discussed. See, Specification, page 14. For example, the pupil diameter can be optimized to dilate no more than five millimeter in dim light and be constricted to as small as one millimeter in bright light. See, Specification, page 4, lines 1-8.

In view of same, clearly nowhere does *Galin* disclose or arguably suggest an ophthalmic formulation that includes an alpha 1 antagonist wherein the formulation is capable of optimizing pupil diameter in dim light by minimizing its dilation in response to less light and further capable of generating a redness response of about +1 or less on the scale of 0 to +4 as required by the claimed invention. Again, *Galin* merely relates to the fixation of intraocular lenses. This is clearly deficient with respect to the ophthalmic formulation features as required by claim 1. Therefore, Applicant believes that *Galin* fails to anticipate or arguably fails to render obvious the claimed invention.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In the Office Action, claims 41 and 42 are rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,515,295 ("*Dougherty*"). The Patent Office essentially asserts that *Dougherty* discloses or suggests each and every feature of the claimed invention as defined by claims 41 and 42.

Applicant believes that this rejection is improper. Of claims 41 and 42, claim 41 is the sole independent claim. Claim 41 relates to an eye dropper that includes a hollow cylindrical barrel. The barrel includes a first end, a second end, and an inner surface. The eye dropper further includes means for providing suction to draw an aqueous formulation into the hollow cylindrical barrel wherein the first end is configured to receive means for providing suction to draw the formulation and wherein the barrel has a small opening at the second end configured to permit passage of the formulation. As amended, claim 41 further recites that the formulation includes an aqueous solvent and a compound that includes an alpha 1 antagonist capable of interfering with a biochemical reaction which results in stimulation of dilator muscles of a human eye and elicits a redness response in a human eye of +1 or less on a scale from 0 to +4.

The formulation of the eyedropper can act to optimize pupil diameter, such as reducing pupil diameter in dim light, without undesirable side effects. See, Specification, page 6, lines 1-9. The formulations include an alpha 1 antagonist which can block the effect of an endogenous compound that stimulates a dilator muscle of a human eye. Thus, the formulation can act to decrease the difference between the diameter of pupil dilation in dim light and the diameter of pupil dilation in bright light as previously discussed.

In contrast, nowhere does *Dougherty* disclose or suggest at least a number of features of the claimed invention. For example, *Dougherty* fails to disclose or suggest the alpha 1 antagonist formulation features of the claimed invention. Indeed, *Dougherty* merely relates to an eyedropper with a light source. In this regard, it places no emphasis or particularity with respect to the type of formulations associated with the eyedropper. As previously discussed, the alpha 1 antagonist formulations of the claimed invention can be effectively utilized to enhance vision by optimizing pupil diameter, such as reducing pupil diameter in dim light. Based on at least these noted differences between *Dougherty* and the claimed invention, Applicant does not believe that one skilled in the art would be inclined to modify *Doughterty* to include the alpha 1 antagonist formulation features of the claimed invention. For at least these reasons, Applicant respectfully submits that *Doughterty* fails to render obvious the claimed invention.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

In the Office Action, claims 29-36 and 41-42 are provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 7-15 and 20-21 of co-pending Application No. 09/705,526. Although Applicant does not agree with this rejection, in the spirit of cooperation and to expedite prosecution thereof, Applicant respectfully submits that upon notice of allowability of either one of the co-pending applications the claims at issue with respect to this rejection in at least one of the co-pending applications will be cancelled or amended to address this rejection. Therefore, Applicant believes that he has been fully responsive to the provisional rejection at this stage.

For the forgoing reasons, Applicant respectfully submits that the present application is now in condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1, 10, 23, 34, 37, 41 and 43 have been amended as follows:

1. (Amended) An ophthalmic formulation, comprising:

a first active compound ~~characterized by (a) its ability to~~including an alpha 1 antagonist capable of reduceing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent the compound and ~~(b)~~ generating a redness response of about +1 or less on a scale of 0 to +4.

10. (Amended) A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising a first compound including an alpha 1 antagonist capable of ~~characterized by its ability to~~ disrupting an endogenous compound which stimulates a dilator muscle of the eye; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation;

wherein the formulation as administered to a human eye elicits a redness response rating of +1 or less.

23. (Amended) A method of modulating pupil dilation, comprising:

administering to an eye of a patient a formulation comprising a compound ~~characterized by (a) its ability to~~including an alpha 1 antagonist capable of disrupting endogenous compounds which stimulate dilator muscles of the eye and ~~(b)~~ eliciting a redness response of +1 or less on a scale of from 0 to +4; and

allowing the formulation to remain in contact with the eye for a period of time and under lighting conditions where the dilator muscles would be stimulated in the absence of the formulation.

34. (Amended) A method of treatment, comprising:

subjecting the eye of a human patient to refractive surgery;

allowing the eye of the patient to recover; and

administering to the patient a formulation comprised of an active agent ~~which~~including an alpha 1 antagonist capable of blocksing an endogenous compound which stimulates a dilator muscle of the eye wherein the formulation is a liquid formulation applied directly to the eye of the patient.

37. (Amended) An ophthalmic, night vision formulation, comprising:

a sterile aqueous carrier;

a therapeutically effective amount of a first pharmaceutically active compound including an alpha 1 antagonist capable of ~~characterized by its ability to~~ disrupting endogenous compounds which stimulate dilator muscles of a human eye; and

a second pharmaceutically active compound characterized by its ability to reduce redness in a human eye.

41. (Amended) An eyedropper, comprising:

a hollow cylindrical barrel comprising a first end, a second end, and an inner surface;

a means for providing suction to draw an aqueous formulation into the hollow cylinder barrel, the first end of the barrel configured to receive the means for providing suction to draw the formulation, the barrel having a small opening at the second end configured to permit passage of the formulation;

wherein the formulation comprises an aqueous solvent and a compound ~~characterized by (a) its ability to~~including an alpha 1 antagonist capable of interfereing with a biochemical reaction which results in stimulation of dilator muscles of a human eye, and ~~(b)~~ eliciting a redness response in a human eye of +1 or less on a scale of from 0 to +4.

43. (Amended) A method of reducing adverse visual effects of spherical aberrations on a human eye, comprising:

administering to a human eye a first active compound ~~characterized by (a) its ability to~~ including an alpha 1 antagonist capable of reduceing dilation of a human eye exposed to a low light environment as compared to dilation which naturally occurs absent the compound and ~~(b)~~ generating a redness response of about +1 or less on a scale of 0 to +4.